Food and Drug Administration, HHS

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2582 Triflupromazine hydrochloride injection.

- (a) Specifications. Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.
- (b) Sponsor. See No. 053501 in \$510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.¹
- (2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams. ¹
- (3) Not for use in horses intended for food. 1
- (4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentitate the toxicity of organophosphates and the activity of procaine hydrochloride. ¹
- (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹
- [40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine.

- (a) Specifications. Each milliliter (mL) contains:
- (1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or
- (2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).
- (b) *Sponsors*. See Nos. 000061 and 000856 in §510.600(c) of this chapter.
- (c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Conditions of use—(1) Dogs—(i) Amount. 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.
- (ii) Indications for use. For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to Streptococcus zooepidemicus.
- (2) Horses—(i) Amount. 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.
- (ii) Indications for use. For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.
- (iii) *Limitations*. Not for use in horses intended for human consumption.

 $[71 \ FR \ 30803, \ May \ 31, \ 2006]$

§ 522.2615 Tripelennamine hydrochloride injection.

- (a) Specifications. Each milliliter of aqueous solution contains 20 milligrams of tripelennamine hydrochloride
- (b) Sponsor. See Nos. 000859 and 053501 in $\S510.600(c)$ of this chapter.
- (c) Related tolerances. See §556.741 of this chapter.

¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by §514.111 of this chapter, but may require bioequivalency and safety information